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10/555,109

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Jian-Yun Dong

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EXAMINER

HIRIYANNA, KELAGINAMANE T

ART UNIT

PAPER NUMBER

1633

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/555,109	<b>Applicant(s)</b> DONG ET AL.	
	<b>Examiner</b> KELAGINAMANE T. HIRIYANNA	<b>Art Unit</b> 1633	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) 20-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>05/2007 &amp; 05/2007</u> .                                   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicant's response filed on 09/30/2009 in response to office action mailed on 03/30/2009 has been acknowledged.

*Applicants are required to follow Amendment Practice under revised 37 CFR §1.121. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.*

### **Restriction of invention**

Applicant's election without traverse of restriction requirement in the reply filed on March 30, 2009 is acknowledged. Applicant elects without traverse the invention Group I (Claims 1-19) for further prosecution on merits. Applicants' election of species is noted.

Claims 1-19 are pending and presently under examination.

Claims 20-53 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected claims, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 09/30/200.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 contains the recitation of the limitation on line 1 "derived from ....promoter" (TSREs from various promoter structure possibilities of each species of promoter listed). Such limitation, by using the term "derived" makes the claim so broad as to lack of clarity, as it includes any derivation, essentially making any new sequence arrived at by any method a derived structure. Hence, the claim is rejected for lack of clarity.

### Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

"The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention."

Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The scope of invention as claimed encompasses using multiple TSRE structural derivatives from each of the promoter listed in claim 13 and hence implied to be encompassed by the base claim.

The specification, however only teaches using a single TSRE structure obtained from or contained in the ARR2PB promoter.

The application does not disclose any other TSRE structure other than the single TSRE structure obtained from or contained in the ARR2PB promoter. Further the applicant only lists the name of different promoter from which a corresponding TSRE element is obtained. No other TSRE structural derivatives of any of the promoter listed has been described.

Applicant is referred to the guidelines for ***Written Description Requirement*** published January 5, 2001 in the Federal Register, Vol.66, No.4, pp.1099-1110 (see <http://www.uspto.gov>). The disclosure of a single species is rarely, if ever, sufficient to describe a broad genus, particularly when the specification fails to describe the features of that genus, even in passing. In analyzing whether the written description requirement is met for the genus claim, it is first determined whether a representative number of species have been described by their complete structure. Next, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics.

Since the specification fails to disclose the different TSRE structural derivatives obtained the claimed promoters, it is not possible to envision the structures of the broadly claimed TSRE derivatives of each of the promoters could be used as a valid TSRE element in the vector constructs claimed. One cannot describe what one has not conceived. Therefore, the lack of disclosure in the specification is not deemed sufficient to reasonably convey to one skilled in the art that the applicants were in possession of the huge genera recited in the claims at the time the application was filed. Furthermore the possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics (as it relates to the claimed invention as a whole) such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Accordingly one of skill in the art would conclude that applicant was not in possession of the claimed genus because a description of a single member of this genus would not be representative of claimed genus of compounds and is insufficient to support the claim in its present scope.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 5-19 are rejected under 102(b) as being anticipated by Rubinchik et al., (2001, Molecular Therapy 4:416-426; art of record).

The above claims are drawn to an expression vector comprising a first expression cassette encoding a transcriptional activating factor under the transcriptional control of a first promoter comprising a tissue specific regulatory element and a transcriptional

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activator binding site and a second expression cassette that encodes a selected peptide under the transcriptional control of a second promoter comprising a tissue specific regulatory element and a transcriptional activator binding site or a binding site.

Rubinchik teaches an Adenoviral expression vector comprising two expression cassettes, the first expression cassette comprises tetracycline transactivator gene (a TAF) under the transcriptional control of ARR2PB promoter (an androgen regulated prostate tissue specific promoter) and said promoter comprises a transcriptional activator binding site and the second expression cassette comprises Tnfsf6-GFP fusion gene (encoding a tumor therapeutic polypeptide, an inducer of apoptosis) under the transcriptional control a tetracycline responsive promoter comprising tetracycline transactivator binding site.(entire article; abstract; p.418, col.2 bridging p.419-424). Rubinchik teaches replication-deficient and conditionally replication-competent Adenoviral viral vector constructs and viral particles (entire article; p.417 Fig.1).

### ***Claim Rejections - 35 USC § 102 & 35 USC § 103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-19 are rejected under 102(e) as being anticipated by Phillips et al., (US 2004/0161847).

Claims 1-19 are rejected under 35 USC 103 (a) as being unpatentable over Phillips et al., (US 2004/0161847).

The above claims are drawn to an expression vector comprising a first expression cassette encoding a transcriptional activating factor under the transcriptional control of a first promoter comprising a tissue specific regulatory element and a transcriptional activator binding site and a second expression cassette that encodes a selected peptide under the transcriptional control of a second promoter comprising a tissue specific regulatory element and a transcriptional activator binding site or a binding site.

Phillips teaches "vigilant vectors system" with a single or double vector comprising expression cassettes comprising coding regions that encode a transcriptional activating factors (example oxygen sensitive transactivator under a tissue specific promoter of hMLC gene (which consists of a TAF binding site) and the second cassette that comprises nucleotide sequence encoding a therapeutic gene (e.g. a cardioprotective gene) under the control of a transactivator inducible promoter that contained a TAF binding site. Phillips however, teaches a strategy placing the two cassettes one encoding the transactivator and the other encoding the therapeutic peptide on two different plasmids or viral vectors and their co-transfection to cells for amplified tissue specific expression (p.265, col.2, 2<sup>nd</sup> paragraph). However given the general knowledge in the prior art regarding gene expression construct technology at the time of invention, the two cassettes could have been expressed to achieve the same result by incorporating them in to a single vector molecule. Thus, Phillips et al anticipates the invention as claimed.

Further it would have been obvious for one of ordinary skill in the art to incorporate the two plasmid or viral vigilant that system of Phillips that upregulates the tissue specific expression of a therapeutic gene in to a single plasmid or viral vector comprising both the cassettes for transactivator amplification and tissue specific expression and use it for treating a cancer. One of ordinary skill in the art would have been motivated to make and use a single vector capable of amplified expression of both the transactivator and the therapeutic protein, as this would solve the unpredictability of transfecting two independent vectors in to the same cell for co-operative expression. One of ordinary skill in the art would have reasonable expectation of success making using a single vector system for expressing both the transactivator and therapeutic gene as the the art at the time of invention teaches that is it is routine to use a single vector constructs with dual

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expression cassettes for co-operative or co-ordinate expression in a target cell. Thus, the claimed invention was *prima facie* obvious.

***Conclusion:***

No claim allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Kelaginamane Hirianna Ph.D.*, whose telephone number is **(571) 272-3307**. The examiner can normally be reached Monday through Thursday from 9 AM-7PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Joseph Woitach Ph.D.*, may be reached at **(571) 272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). When calling please have your application serial number or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. For all other customer support, please call the USPTO call center (UCC) at (800) 786-9199.

/Robert M Kelly/

Primary Examiner, Art Unit 1633